

1 Reason for the review

Orlistat is a lipase inhibitor which reduces the absorption of dietary fat. It is prescribed as an anti-obesity drug, in conjunction with a mildly hypocaloric diet rich in fruit and vegetables, for individuals over 18 years of age with a BMI of 30kg/m² or more, or in individuals with a BMI of 28kg/m² in the presence of other risk factors e.g. Type 2 diabetes, hypertension or hypercholesterolaemia. It should only be used where diet, physical activity and behavioural changes are supported. Treatment should continue beyond 12 weeks only if the patient has lost at least 5% of initial body weight.¹

NICE advises that less strict goals may be appropriate for people with type 2 diabetes and these goals should be agreed with the person and reviewed regularly². Antidiabetic medicinal product treatment may have to be closely monitored when taking orlistat³.

Beyond 12 months therapy may continue if there are clinical benefits and the potential benefits and risks have been discussed with the patient¹. SIGN 115 suggests that these clinical benefits may include the prevention of significant weight regain so may involve medication use outside current licence.⁴ The XENDOS trial used a four year treatment period with no adverse effects for long term use reported⁵.

Drug treatment should be discontinued if the individual regains weight at any time whilst receiving treatment¹

2 Inclusion Criteria

Search for all patients prescribed the following on repeat prescription within the last 6 months:

- Orlistat
- Xenical®

3 Exclusion Criteria

- Any specified by the GP practice

4 Preparation and planning

Implementation of audit in selected GP practices is as follows:

- Protocol to be discussed with all GPs in the practice to ensure that agreement to proceed is reached
- Frequency of weight checks after the 12 week review to be decided with GP practice
- Computer search of all patients according to the inclusion criteria
- Review of patients medical notes and repeat prescribing records
- List of eligible patients to be checked by GP/GPs for any further action
- Letter to be sent to patients due for review of treatment and/or repeat measure of weight
- Medication to be discontinued where patient has gained weight, or has failed to lose ≥5% of initial body weight in accordance with criteria outlined in the introduction

5 Action

- Letters written to all patients due for review of weight and information provided to support their treatment. Patient to be fully informed if treatment is to be discontinued.
- Admin staff in practices to be made aware of change of repeat medication
- Report for practices will include number of reviews flagged up by the pharmacist/technician

6 Criteria and standards

Criteria

- Patients should have initial BMI $\geq 30\text{kg/m}^2$ or BMI $\geq 28\text{kg/m}^2$ in presence of additional risk factors
- Patients should have weight recorded at first visit and BMI calculated
- Patients should be reviewed after 12 weeks and weight re-measured
- At 12 week review patient's weight loss should be $\geq 5\%$ for treatment to continue
- Treatment should be continued beyond 12 months only if weight has not increased and risk/benefits have been discussed with patient
- Patients should not gain weight at any time during treatment

Standards

- 100% of patients to meet licensed criteria for prescribing (ie, BMI $\geq 30\text{kg/m}^2$ or BMI $\geq 28\text{kg/m}^2$ in presence of additional risk factors)
- 100% of patients to have weight recorded and BMI calculated before treatment commences
- 100% of patients to be called for 12 week review and weight change calculated
- 100% of patients to have lost $\geq 5\%$ of initial body weight at 12 weeks if treatment is to be continued
- 100% of patients on treatment longer than 1 year to have risk benefit of continuing treatment discussed
- 0% of patients who gain weight have treatment continued

7 References

1. British National Formulary (BNF) No.59 March 2010 Pharmaceutical Press
2. NICE guidelines CG43 Obesity Dec 2006 www.guidance.nice.org.uk/CG43
3. Xenical® SPC www.medicines.org.uk/emc/medicine/1746/xenical
4. Scottish Intercollegiate Guidelines Network (SIGN) 115 Management of obesity. Edinburgh, SIGN 2010
5. Torgerson JS et al. Xenical in the prevention of diabetes in obese subjects (XENDOS) study. Diabetes Care 2004; 27: 155-161

Review to be undertaken by:GP Authorisation: Date:

Patient name
Address

Dear Mr/Mrs _____

As part of a review of prescribing, NHS Dumfries and Galloway is currently reviewing all patients prescribed the anti-obesity medicine **orlistat (sometimes known as Xenical®)**

It is important when taking this medication that your weight is monitored regularly and treatment may be continued/discontinued as appropriate. You should also have access to support with other lifestyle measures such as a suitable diet, increasing physical activity, smoking cessation.

Please contact your surgery to arrange an appointment with.....for.....

Should have any queries, please do not hesitate to contact the Surgery on the number above or, alternatively, you can contact a member of the Prescribing Support Team on

Yours sincerely,

Name

Prescribing Support Technician
On behalf of the Doctors

